The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board.

Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CLAUS WEISEMANN, WOLFGANG KREISS, HANS-GEORG RAST and GUNTHER EBERZ

Appeal No. 1997-3898 Application No. 08/116,382¹

HEARD: November 16, 2000

Before ROBINSON, SPIEGEL, and SCHEINER, <u>Administrative Patent Judges</u>. SPIEGEL, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 8 through 17, which are all of the claims pending in this application. Claim 8 is illustrative and reads as follows.

8. An analytic process for testing for the presence of toxic components in a mixture of components, said process comprising separating said mixture into separate components by chromatography in a chromatographic system, directly contacting a separated component with a

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¹ Application for patent filed September 2, 1993.

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strain of luminescent microorganism within the chromatographic system itself, and determining a reduction in the luminescence of said microorganisms, said reduction in the luminescence of said microorganisms indicating that said separated component is toxic.

The references relied on by the examiner are:

Jordon et al. (Jordon)	3,370,175	Feb. 20, 1968
Bostick et al. (Bostick)	4,357,420	Nov. 2, 1982
Drucker et al. (Drucker)	WO 85/00890	Feb. 28, 1985
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(published international application)

Bjorseth et al. (Bjorseth), "Detection of Mutagens in Complex Samples by the <u>Salmonella</u> Assay Applied Directly on Thin-Layer Chromatography Plates," <u>Science</u>, Vol. 215, No. 4528, pp. 87-89 (1982)

ISSUE

Claims 8 through 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Jordon or Drucker in view of Bjorseth and Bostick. We REVERSE.

In reaching our decision in this appeal we have given careful consideration to the appellants' specification and claims and to the respective positions articulated by the appellants and the examiner. We make reference to the Examiner's Answer (Paper No. 21, mailed May 8, 1997) for the examiner's reasoning in support of the rejection and to the appellants' Brief (Paper No. 18, filed February 10, 1997), request for reconsideration and declaratory evidence (Paper Nos. 19 and 20, filed May 6, 1997) and Reply Brief (Paper No. 23, filed August 12, 1997) for the appellants' arguments thereagainst.

BACKGROUND

Contacting a mixture of various chemical compounds with luminescent bacteria to test for toxicity as determined by a change in the luminescence of the bacteria is known (specification, p. 1, II. 1-12). However, no information was provided as to which individual component(s) of the mixture was responsible for the toxicity (specification, p. 1, II. 12-14). The claimed invention is drawn to a method wherein the mixture is first separated into its components by chromatography, the separated components are contacted with the luminescent bacteria and the toxicity of individual components is determined by measuring luminescence (specification, p. 1, II. 23-29) (claim 8). Claims 9 through 12 relate to thin layer chromatographic separation of the test mixture. Claims 13 through 17 relate to liquid chromatographic separation of the test mixture.

OPINION

To establish a <u>prima facie</u> case of obviousness, there must be both some suggestion or motivation to modify the reference or combine reference teachings and a reasonable expectation of success. Furthermore, the prior art must teach or suggest all the claim limitations. <u>In re Vaeck</u>, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Jordon detects toxins in a gas or aerosol by contacting a test sample with, e.g., by flowing an air sample over, a solid culture of luminescent microorganisms which undergo

a change in luminescence when exposed to toxic gases (c. 1, II. 35-50; c. 2, II. 44-61; c. 3, II. 51-53). Jordon does not detect individual toxins. Drucker, on the other hand, selectively detects the presence or absence of a specific chemical toxin in a gas, liquid or on solid sample using a pair of toxin-sensitive and toxin-resistant mutant substrains genetically derived from the same parental strain of bioluminescent microorganisms having luminescent outputs which are unaffected by the presence of other chemical toxins than the toxin selected for (p. 1, II. 2-10; p. 3, II. 10-17).

Bjorseth uses thin layer chromatography (TLC) to separate complex mixtures into individual components and uses the Ames <u>Salmonella</u> test to detect mutagenic chemicals directly on the TLC plates (para. bridging pp. 87-88).

Bostick detects selected biomarkers isolated from complex biological samples by chromatography by contacting a sample of effluent with biomarker specific reactants to generate a bioluminescent signal correlative of the concentration of the specific biomarker (c. 3, II. 8-59). Example 1 illustrates determination of creatine kinase by a luciferase enzymatic reaction (ccs. 4-5).

According to the examiner, it would have been obvious to use the TLC separation and direct assay method of Bjorseth in the toxicity assay of either Jordon or Drucker to provide simultaneous assay of multiple toxins in a single sample and to identify individual toxins given Bostick's generic "concept of chromatographic separation and subsequent

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luminescent organism detection of different separated elutes for toxicity determination" (Answer, para. bridging pp. 4-5). The examiner further concluded that substituting the bioluminescent toxicity assay of either Jordon or Drucker for the mutagenicity <u>Salmonella</u> assay of Bjorseth "would have been an obvious modification" (Answer, p. 6, II. 1-4).

However, the examiner has failed to explain why one of ordinary skill in the art would have added a specific separation and identification step to the method of Jordon given Jordon's explicit direction towards rapid detection of a broad variety of toxins as opposed to specific toxins.² Similarly, the examiner has failed to explain why the skilled artisan would have added a specific separation and identification step to the method of Drucker given the toxin-specific nature of the mutant bioluminescent microorganisms used by Drucker. The examiner has failed to explain how and why the skilled artisan would have changed the mutagencity test of Bjorseth into a toxicity test, especially in view of Bjorseth's

It is therefore a broad object of this invention to provide a toxicant detector for low concentrations of a broad variety of toxic materials.

² See e.g., Jordon at c. 1, II. 13-29

Rapid detection of toxic agents in gaseous or aerosol form is a substantial problem for many industrial applications to warn personnel of sudden escapes of toxicants or detect accumulations of toxicants in working areas. Several techniques are suitable for detection systems but many of these do not find ready adaptation to field use due to problems of reliability, maintenance, ruggedness, speed of response, size, weight, and the like. In addition most of the systems are highly specific in that they detect the presence of single toxic materials or limited classes of toxic materials. A system capable of detecting small quantities of one toxic agent may be almost completely insensitive to another toxicant which may occur in the same environment.

explicit suggestion to remove interference from toxins on the disclosed mutagencity test.³ Finally, the examiner has not pointed out, and we do not find, where Bostick provides the requisite motivation to combine the disclosures of the prior art as suggested. Rather, the examiner simply relies on Bostick to show that chromatographic separation and luminescent detection of components of a mixture is known (Answer, p. 9, II. 1-3).

Thus, we find the examiner has not carried his burden of establishing a <u>prima facie</u> case of obviousness and has relied on impermissible hindsight in making his determination of obviousness. <u>In re Fritch</u>, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.). Having concluded that the examiner has not established a <u>prima facie</u> case of obviousness, we do not reach the Weisemann Declaration discussed in appellants' request for reconsideration.

Accordingly, based on this record, the rejection of claims 8 through 17 under 35 U.S.C. § 103(a) over Jordon or Drucker in view of Biorseth and Bostick is reversed.

³ See e.g., Bjorseth at p. 89, i.e., "Toxic compounds may then be separated from the mutagenic compounds and thereby not interfere with the mutagenicity test" (c. 1, II. 3-6 from the bottom) and "Because the compounds are separated, effects arising from toxic substances in the sample may, in principle, be avoided" (sentence bridging ccs. 2-3).

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CONCLUSION

To summarize, the decision of the examiner to reject claims 8 through 17 under 35 U.S.C. § 103(a) as being unpatentable over Jordon or Drucker in view of Bjorseth and Bostick under 35 U.S.C. § 103 is reversed.

REVERSED

DOUGLAS W. ROBINSON Administrative Patent Judge)))
CAROL A. SPIEGEL Administrative Patent Judge)) BOARD OF PATENT) APPEALS) AND) INTERFERENCES)
TONI R. SCHEINER Administrative Patent Judge)))

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KURT G. BRISCOE, ESQ. SPRUNG, KRAMER, SCHAEFER & BRISCOE 660 WHITE PLAINS ROAD TARRYTOWN, NY 10591-5144

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